REMARKS

Claims 22-31 are pending in this application. Claims 1-21 have been canceled without prejudice or disclaimer. Claim 27 has been amended. Claims 28-31 has been newly added.

Applicant, by canceling or amending any claims herein, makes no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicant reserves the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Claim 27 has been amended to correct dependency. Specifically, claim 27 now depends from claim 24. Support for this amendment can be found throughout the specification and claims as originally filed.

Claim 28 has been newly added. New claim 28 is directed to the "method according to claim 22, wherein the topical skin preparation further comprises one or more pharmaceutically acceptable additive." Support for new claim 28 can be found throughout the specification and claims as originally filed.

Claim 29 has been newly added. New claim 29 is directed to the "method according to claim 28, wherein the one or more pharmaceutically acceptable additive is selected from the group consisting of a preservative, an antioxidant and a perfume." Support for new claim 29 can be found throughout the specification and claims as originally filed.

Claim 30 has been newly added. New claim 30 is directed to the "method according to claim 22, wherein the testosterone phenyl propionate is present in a concentration of

from 0.1 to 1% by weight of the total preparation." Support for new claim 30 can be found throughout the specification and claims as originally filed.

Claim 31 has been newly added. New claim 31 is directed to the "method according to claim 27, wherein the testosterone phenyl propionate is present in a concentration of 1% by weight of the total preparation." Support for new claim 31 can be found throughout the specification and claims as originally filed.

No new matter has been added.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

I. Interview

Applicant thanks Examiners Basquill and Fetterolf for conducting an interview with Applicant's undersigned representative on July 9, 2009. During the interview each of the rejections were discussed as well as arguments traversing the same.

II. At page 3 of the Official Action, claim 27 has been rejected under 35 USC § 112, second paragraph.

The Examiner asserts that claim 27 is improper because there is no antecedent basis for the phrase "the testosterone phenyl propionate."

In view of the remarks set forth herein, this rejection is respectfully traversed.

Claim 27 has been amended to correct dependency. As amended, claim 27 now depends from claim 24, which provides antecedent basis for the phrase "the testosterone phenyl propionate."

Accordingly, Applicant submits that claim 27 is clear and definite within the meaning of 35 USC § 112. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

III. At page 3 of the Official Action, claims 22-23 have been rejected under 35 USC § 103(a) as being unpatentable over Mazer et al. (US Patent No. 6,583,129) in view of Shouls

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to combine the teachings of Shouls et al. with that of Mazer et al. to arrive at the presently claimed subject matter because both the testosterone derivatives of Mazer et al. and the testosterone phenyl propionate of Shouls et al. have been indicated as suitable for transdermal therapy.

In view of the following, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U. S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in

the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

With regard to motivation to combine references, **MPEP 2143** discusses the requirements of a *prima facie* case of obviousness. First, there must be some suggestion or motivation to combine the reference teachings or to modify the reference, and second, there must be a reasonable expectation of success. Finally, the prior art reference or references when properly combined, must teach or suggest all the claim limitations.

Regarding motivation to modify properly combined references, **MPEP 2143.01** states that a proposed modification cannot render the prior art unsatisfactory for its intended purpose. If it does, then there is no suggestion or motivation to make the proposed modification. Further, the proposed modification cannot change the principle operation of a reference.

Regarding *teaching away*, **MPEP 2141.02** states that prior art must be considered in its entirety, including disclosures that *teach away* from the claims. See also **MPEP 2145(X)(D)**. The Federal Circuit in *Takeda v. Alphapharm* found that the prior art taught

away from the closest compound because the prior art in fact disclosed a broad selection of compounds where the closest prior art compound exhibited negative properties that would have led the skilled artisan away from that compound.

Applicant respectfully submits that a *prima facie* case of obviousness has not been established because, whether taken alone or in combination, none of the cited references teach or suggest each and every element of the presently pending claims, and there is no motivation to modify the topical formulation of Mazer et al. with the testosterone propionate described in Shouls et al.

Claim 22 is directed to a method for treating atrophy or aging of skin in women, comprising: administering to a female subject in need thereof, a topical skin preparation comprising a testosterone ester of an acid having between six to eleven carbon atoms, provided that the topical skin preparation does not comprise estrogen or estrogen derivatives. Claims 23 depends from claim 22.

In contrast to the presently pending subject matter, Mazer et al. is directed to compositions, methods, and kits to treat women with elevated SHBG levels, or women receiving oral estrogen supplementation, by administering an amount of an androgenic steroid. *See* Mazer et al., at the abstract. Unlike the presently claimed subject matter, Mazer et al. do not teach or suggest a method for the treatment of atrophy or aging of the skin, as recited in present claim 22. Accordingly, Mazer et al. do not teach or suggest administering to the specific patient population recited in the present claims.

In this regard, Applicant notes while claim 1 of Mazer et al. recites "a method of improving health" it does not teach a method for the treatment of atrophy or aging of the skin as recited in present claim 22. As defined in column 8, lines 39-51, of Mazer et al., the phrase "improving health" refers to various health conditions which are not specifically related to atrophy or aging of the skin. In this regard, according to Mazer et al.:

> 'Improving health' refers to reducing, improving, or preventing the incidence and/or intensity of symptoms associated with androgenic steroid deficiency. Examples of such symptoms include but are not limited to: sexual dysfunction, which can manifest in loss of sexual desire, decreased sensitivity to sexual stimulation, decreased arousability and capacity for orgasm, diminished vital energy, depressed mood, diminished sense of well-being, increased shyness, loss of muscle mass and function, unfavorable body composition, i.e., lean to fat mass ratio, thinning and loss of pubic hair, urogenital atrophy, dry and brittle scalp hair, dry skin, decreased cognitive abilities, dry eyes, autoimmune phenomena, and a combination thereof. *See* Mazer et al. at column 8, lines 39-51.

Applicant respectfully submits that nowhere in Mazer et al. is a method for the treatment of atrophy or aging of the skin taught or suggested.

In addition, Applicant submits that Mazer et al. also do not teach or suggest each or suggest the administration of a topical skin preparation which ***does not comprise estrogen or estrogen derivatives***, as recited in claim 22. Further Applicant submits that nowhere Mazer et al. is there a teaching or suggestion of treating atrophy or aging of the skin in women with a topical formulation comprising testosterone phenlypropionate

Shouls et al. do not remedy the deficiencies of Mazer et al. Shouls et al. describe contact allergies associated Andropatch®, i.e., a testosterone containing transdermal patch. The Examiner seems to read improperly read Shouls et al. as describing a topical

therapeutic formulation comprising testosterone phenyl propionate. In fact, Applicant submits that Shouls et al. does not provide any teaching or suggestion that testosterone phenyl propionate is an effective therapeutic agent for anything, especially a topical formulation for treating skin atrophy or aging in women.

Like Mazer et al., Shouls et al. do not teach or suggest a topical formulation (with therapeutic activity) for treating atrophy or aging in women that comprises testosterone phenyl propionate, as presently claimed.

With regard to testosterone phenyl propionate, nowhere in Shouls et al. is testosterone phenyl propionate taught or suggested in a transdermal dosage form with therapeutic activity. In this regard, Applicant respectfully reminds the Examiner that a patch test is an allergy test where a very small amount of a substance is placed on the skin and observed for an adverse topical reaction. A patch test does not demonstrate any therapeutic effect. Therefore, ***at most***, Applicant submits ***Shouls et al. merely shows that it may be possible to take an injectable formulation and place it in contact with skin to try to elicit an allergic effect***.

Applicant submits that Shouls et al. does not show that Sustanon had any activity, topical or otherwise. In this regard, Applicant notes that Table 1 of Shouls et al. indicates that no reaction was elicited by the administration of Sustanon, topical or otherwise, which, as best, indicates that if Sustanon were applied topically it had no effect because ***no reaction or activity was observed***.

Furthermore, Applicant respectfully submits that just because something can be make contact with the skin, it would not inherently suggest that that thing would be effective as a therapeutic topical agent. Such a construction would mean that any form of matter could be considered as being a topical formulation form because any matter could, in theory, come in contact skin.

Applicant further submits that there would be no motivation to modify Mazer et al. with Shouls et al. to arrive at the present subject matter because, with specific regard to claim 23, there would be no reasonable expectation of success. In this regard, nowhere is it taught or suggested that testosterone phenyl propionate has any therapeutic effect when applied topically. Accordingly, Applicant submits that the presently claimed subject matter is not obvious in view of the cited art.

In view of the remarks set forth herein, it is submitted that, whether taken alone or in combination, Mazer et al. and Shouls et al. do not render claims 22-23 obvious within the meaning of 35 USC § 103 (a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

IV. At page 4 of the Official Action, claims 22-26 have been rejected under 35 USC § 103(a) as being obvious over Mazer et al. in view of De Nijis et al. (US Patent Application No. 2005/0101517) and Friedman (US Patent No. 6,004,566).

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to combine Mazer et al. with De Nijis et al. and Friedman et al. to arrive at the presently claimed subject matter because it would have been obvious to utilize the testosterone phenyl propionate described in De Nijis et al. in amounts taught in Friedman et al. in the

composition described by Mazer et al. and because the testosterone phenyl propionate of Shouls et al. has been indicated as suitable for transdermal therapy.

In view of the following, this rejection is respectfully traversed.

An outline of the relevant authority regarding obviousness is set forth above. The discussion of the relevant authority is incorporated herein by reference.

Applicant respectfully submits that a *prima facie* case of obviousness has not been established because, whether taken alone or in combination, none of the cited references teach or suggest each and every element of the presently pending claims, and there is no motivation to modify the references to arrive at the presently claimed subject matter.

As discussed above, claim 22 is directed to a method for treating atrophy or aging of skin in women, comprising: administering to a female subject in need thereof, a topical skin preparation comprising a testosterone ester of an acid having between six to eleven carbon atoms, provided that the topical skin preparation does not comprise estrogen or estrogen derivatives. Claims 23-26 depend, either directly or indirectly, from claim 22.

Mazer et al. is discussed above in detail. The discussion of Mazer et al. is incorporated herein by reference. As discussed, In contrast to the presently pending subject matter, Mazer et al. is do not teach or suggest treating atrophy or aging of the skin in the patient population presently claimed, namely women in need thereof. In addition, Applicant submits that Mazer et al. also do not teach or suggest each or suggest the administration of a topical skin preparation which ***does not comprise estrogen or estrogen derivatives***, as recited in claim 22. Further Applicant submits that nowhere in Mazer et al. is there a teaching or suggestion of treating atrophy or aging of the skin in

women with a topical formulation comprising testosterone phenlypropionate, as recited in claim 23.

De Nijis et al. do not remedy the deficiencies of Mazer et al. De Nijis et al. is directed to formulations of testosterone decanoate for use in humans. De Nijis et al. merely describe ***an injectable formulation*** which comprises a testosterone derivative. De Nijis et al. do not teach or suggest that the injectable described therein has any topical therapeutic activity

However, whether taken alone or in combination, neither Mazer et al. nor De Nijis et al. teach or suggest: treating the presently claimed patient population; the administration of a topical skin preparation which does not comprise estrogen or estrogen derivatives, as recited in claim 22; and a topical formulation with therapeutic activity which comprise testosterone phenyl propionate, as recited in claim 23. Accordingly, whether taken alone, or in combination, none of the cited references teach or suggest every element of the present claims.

Freidman et al. do not remedy the deficiencies of Mazer et al. and De Nijis et al. Friedman et al. is directed to a delivery system that includes a bioactive drug or cosmetic substance presented in the form of submicron oil spheres alone, or drugs or cosmetic substances in a combination with the oil spheres in an aqueous suspension or emulsion. *See* Friedman et al. at the abstract.

Like Mazer et al. and De Nijis et al., Freidman et al do not teach or suggest: treating the presently claimed patient population; the administration of a topical skin preparation which does not comprise estrogen or estrogen derivatives, as recited in claim 22; and a

topical formulation with therapeutic activity which comprise testosterone phenyl propionate, as recited in claim 23. Accordingly, whether taken alone, or in combination, none of the cited references teach or suggest every element of the present claims.

Applicant further submits that there would be no motivation to modify the cited references to arrive at the present subject matter because, with specific regard to claim 23, there would be no reasonable expectation of success. In this regard, nowhere is it taught or suggested that testosterone phenyl propionate has any therapeutic effect when applied topically. Accordingly, Applicant submits that the presently claimed subject matter is not obvious in view of the cited art.

In view of the remarks set forth herein, it is submitted that, whether taken alone or in combination, Mazer et al., De Nijis et al. and Friedman et al. do not render claims 22-26 obvious within the meaning of 35 USC § 103 (a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

V. At page 5 of the Official Action, claims 22-27 have been rejected under 35 USC § 103(a) as being obvious over Mazer et al. in view of Shouls et al. and Friedman.

The Examiner asserts that it would have been obvious to use the delivery system described by Friedman in the topical treatment of skin disorders described by Mazer et al. as modified by Shouls et al.

In view of the following, this rejection is respectfully traversed.

An outline of the relevant authority regarding obviousness is set forth above. The discussion of the relevant authority is incorporated herein by reference.

Applicant respectfully submits that a *prima facie* case of obviousness has not been established because, whether taken alone or in combination, none of the cited references teach or suggest each and every element of the presently pending claims, and there is no motivation to modify the references to arrive at the presently claimed subject matter.

As discussed above, claim 22 is directed to a method for treating atrophy or aging of skin in women, comprising: administering to a female subject in need thereof, a topical skin preparation comprising a testosterone ester of an acid having between six to eleven carbon atoms, provided that the topical skin preparation does not comprise estrogen or estrogen derivatives. Claims 23-26 depend, either directly or indirectly, from claim 22.

Each of Mazer et al., Shouls et al. and Freidman are discussed above. The discussion of each of the references is incorporated herein by reference. As discussed, Mazer et al. and Shouls et al. do not render the present subject matter obvious because, whether taken alone or together, the cited references do not teach or suggest treating the presently claimed patient population; the administration of a topical skin preparation which does not comprise estrogen or estrogen derivatives, as recited in claim 22; and a topical formulation with therapeutic activity which comprise testosterone phenyl propionate, as recited in claim 23.

Freidman do not remedy the deficiencies of Mazer et al. and Shouls et al. Like Mazer et al. and Shouls et al. Freidman also does not teach or suggest: treating the presently claimed patient population; the administration of a topical skin preparation which does not comprise estrogen or estrogen derivatives, as recited in claim 22; and a topical formulation with therapeutic activity which comprise testosterone phenyl propionate, as

recited in claim 23. Accordingly, whether taken alone, or in combination, none of the cited references teach or suggest every element of the present claims.

Applicant further submits that there would be no motivation to modify the cited references to arrive at the present subject matter because, with specific regard to claim 23, there would be no reasonable expectation of success. In this regard, nowhere is it taught or suggested that testosterone phenyl propionate has any therapeutic effect when applied topically. Accordingly, Applicant submits that the presently claimed subject matter is not obvious in view of the cited art.

In view of the remarks set forth herein, it is submitted that, whether taken alone or in combination, Mazer et al., Shouls et al. and Friedman do not render claims 22-27 obvious within the meaning of 35 USC § 103 (a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

VI. New claims 28-31

Claims 28-31 have been newly added. New claim 28 is directed to the "method according to claim 22, wherein the topical skin preparation further comprises one or more pharmaceutically acceptable additive." New claim 29 is directed to the "method according to claim 28, wherein the one or more pharmaceutically acceptable additive is selected from the group consisting of a preservative, an antioxidant and a perfume." New claim 30 is directed to the "method according to claim 22, wherein the testosterone phenyl propionate is present in a concentration of from 0.1 to 1% by weight of the total preparation." New

claim 31 is directed to the "method according to claim 27, wherein the testosterone phenyl propionate is present in a concentration of 1% by weight of the total preparation."

Applicants respectfully submit that new claims 28-31 are both novel and non-obvious. Accordingly, Applicants respectfully request an indication that all of the pending claims are now allowable.

CONCLUSION

In view of the foregoing, Applicant submits that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP

Susanne M. Hopkins
Registration No. 33,247
Ari G. Zytcer
Registration No. 57,474
Customer No. 20259

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THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
Tel: (703) 548-NATH
Fax: (703) 683-8396